

**R E M A R K S**

All amendments and cancellation of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Final Office Action issued 3/21/08, the Examiner issued several rejections. Each of the rejections is discussed in detail below:

**I. The Claims are Enabled**

The Examiner rejects Claims 26-27 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. In particular, the Examiner states "The state of the art recognizes the CLP model to be a model of intra-abdominal sepsis that produces predominantly gram negative bacteremia and endotoxemia." (Office Action, pg. 4). The Applicants respectfully disagree and submit that the CLP mouse model is a model for both gram-positive and gram-negative sepsis. In particular, the Applicants direct the Examiner to Wrann et al. (J. Immunology 2007, 5940; attached hereto) which clearly indicates the presence of gram-positive organisms in CLP mice. The Applicants submit that the specification provides adequate guidance in the form of the CLP model for sepsis. As the Examiner has acknowledged that "Figure 5 and Example 2 show that anti-C5aR antibody, when administered to mice with CLP-induced sepsis prolonged the survival..." (Office Action, pg. 4). The applicants submit that extrapolating from an animal model, which is commonly accepted as being a good indication of treatment in humans, to treatment of human subjects, is not undue experimentation. As the Examiner has acknowledged, the Examiner's own reference "taught that the CLP model of sepsis is an intra-abdominal sepsis model wherein the time course of mortality is similar to that seen in clinical septic shock." (Office Action, pg. 4). As such, the Applicants submit the specification provides sufficient enablement for the presently claimed invention. Accordingly, the rejection should be withdrawn.

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

## **II. The Claims are not Indefinite**

The Examiner rejects Claims 26-27 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. In particular, the Examiner states “Claim 26 is vague and indefinite in the limitation ‘gram-positive sepsis’ and ‘gram negative sepsis’.” (Office Action, pg. 5). The Applicants respectfully disagree with the rejection. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 26 to recite “sepsis caused by gram-positive bacteria and sepsis caused by gram negative bacteria.” As such, the Applicants submit that the claims are definite and respectfully request that the rejection be withdrawn.

## **III. The Claims are Not Obvious**

The Examiner rejects Claims 26-27 under 35 U.S.C. 103 as allegedly being obvious in light of Huber-Lang et al. (FASEB J., 16:1567 (2002); hereinafter Huber-Lang) in view of Werfel et al. (J. Immunol. 157:1729 (1996); hereinafter Werfel) or Rothermel et al. (Scand. J. Immunol. 52:401 (2000); hereinafter Rothermal) and Read et al. (J. Exp. Med. 182:267 (1995); hereinafter Read). The Applicants respectfully disagree with the rejection. The Huber-Lang reference is a publication of the Applicants own work published within the year before the filing date of the present invention, and therefore, is not prior art. See, e.g., MPEP 2132.01 (“Applicant’s disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a).” In re Katz, 687 F.2d 450 (CCPA 1982)). The present application claims priority to U.S. provisional 60/423,759, filed 11/5/02. There were five inventors for the present application: Peter A. Ward, Niels C. Riedemann, Ren-Feng Guo, J. Vidya Sarma, and Markus Huber-Lang. The Huber-Lang reference issued for publication in October 2002. The Huber-Lang reference lists fifteen authors: Markus S. Huber-Lang, Niels C. Riedemann, J. Vidya Sarma, Ellen M. Younkin, Stephanie R. Mc.Guire, Ines J. Laudes, Kristina T. Lu, Ren-Feng Guo, Thomas A. Neff, Vaishealee A. Padgaonka, John D.

Lambris, L. Spruce, D. Mastellos, Firas S. Zetoune, and Peter A. Ward. A 37 C.F.R. §1.132 Declaration from Dr. Peter A. Ward is now provided indicating that 1) Peter A. Ward, Niels C. Riedemann, Ren-Feng Guo, and Vidya J. Sarma are the only listed authors who contributed to the inventive process relating to the present invention; and that 2) Ellen M. Younkin, Stephanie R. Mc.Guire, Ines J. Laudes, Kristina T. Lu, Thomas A. Neff, Vaishealee A. Padgaonka, John D. Lambris, L. Spruce, D. Mastellos, and Firas S. Zetoune were not involved with the inventive process relating to the present invention, worked under Dr. Ward's supervision and direction, and were listed as co-authors of the publication in order to acknowledge their collaboration in a research program under Dr. Ward's direction. As such, per the MPEP §2132.01, the Huber-Lang reference is not prior art.

**CONCLUSION**

A telephone interview was conducted between Examiner Devi and the undersigned on 11/27/07. During the interview, Examiner Devi suggested claim amendments (reflected above) that would overcome the existing rejections under 35 U.S.C. 112 and 103.

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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